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**GB662482**

Publication Title:

An artificial breast

Abstract:

Abstract of GB662482

662,482. Artificial breasts. BERNARDT, E. H. May 20, 1949 [May 22, 1948; May 7, 1949], Nos. 13555/49 and 13556/49. Class 141. [Also in Group VI] An artificial breast comprises a flexible cell containing a conformable, incompressible, inextensible filler and a gas. As shown in Fig. 3, the cell comprises a convex front wall 17 and a flat rear wall 18 of impervious material sealed together at 19 and containing a liquid or conformable gel 11 and gas 22 at atmospheric pressure. The cell is held within an ordinary brassiere cup 12 provided with a cell retainer 15 and a flap 16. In alternative constructions, the cell may be moulded in one piece and the back wall may be convex or concave. The filler may comprise a plurality of small cells surrounded by a liquid and each containing a conformable filler and gas, or it may comprise a plurality of bits of flexible cellular material, e.g. sponge rubber in liquid. In the construction shown in Fig. 6, the cell 10 is enclosed in a similarly shaped flexible impervious envelope 25 which may also contain a water-absorbent powder, and the liquid filler 11 is in a foaming condition. The liquid may also contain a sealing agent so that it clots if the cell is punctured.

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# PATENT SPECIFICATION

662,482



Date of Application and filing Complete Specification May 20, 1949.

Nos. 13555/49 and 13556/49.

Application made in United States of America on May 22, 1948.

Application made in United States of America on May 7, 1949.

Complete Specification Published Dec 5, 1951.

Index at acceptance:- Classes 81(ii), B4x; and 141, Q2.

## COMPLETE SPECIFICATION

### An Artificial Breast

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### SPECIFICATION No. 662,482.

Page 1, line 1, for "Bernardt" read  
"Bernhardt"

THE PATENT OFFICE,  
24th July, 1952.

unpleasing appearance and the form is  
20 worn to maintain the normal figure or  
outline of the bust. In other instances,  
the forms are worn by women with small  
underdeveloped breasts in order to  
improve their figure.

25 It is important that the form be con-  
formable to the shape of the breast or  
remainder of the breast of the wearer  
and of proper weight so that it may be worn  
for long periods of time without discom-  
fort. Further, the form should be con-  
structed that it constantly and auto-  
matically conforms to the remaining  
breast in shape and appearance, as that  
that breast is affected by the position  
35 assumed by the wearer.

Heretofore, some forms have been made  
of wire reinforced padding, others have  
been made of flexible fabric stuffed with  
a filling such as hair, feathers or  
40 cotton, still others have been molded of  
sponge rubber, in addition, air filled  
sacs and distendible sacs inflated with  
water have been used. These devices all  
have a relatively fixed shape, and a rela-  
tively constant volume, or are rather  
45 inconformable and do not realistically  
reproduce the change in shape and the  
movement of a normal breast. Some of  
the prior devices have been generally

frequently assumed poor position. --  
full slanting diaphragm and often large  
abdomen pushes the usual appliance 70  
higher when the person is seated. To  
counteract this movement, straps engag-  
ing with the corset or girdle are often  
used to pull the appliance downwardly.  
The strain set up by such straps not only 75  
causes discomfort at the shoulders but  
actually seriously interferes with the cir-  
culation of shoulder and arm and because  
of the recent operation often produces  
congestion. Moreover, in many cases, the 80  
prior appliances have been difficult or  
impossible to clean or renovate and when  
so cleaned often lose their original shape  
and present an unsightly appearance.

The present invention aims to overcome 85  
the foregoing difficulties and disadvan-  
tages by providing a form which is more  
natural in appearance and readily con-  
forms to the shape of the natural bust  
regardless of the movements of the wearer, 90  
and that requires no special harness to  
wear.

Another object of the invention is to  
provide a form which is sanitary, and  
which may be washed easily and 95  
repeatedly without adversely affecting its  
wearability.

With these and other objects in view



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## COMPLETE SPECIFICATION

### An Artificial Breast

I, ELLA HEDWIG BERNARDT, a citizen of the United States of America, of 1111, Lexington Avenue, City of New York, State of New York, United States of America, do hereby declare the nature of this invention and in what manner the same is to be performed, to be particularly described and ascertained in and by the following statement:—

10 The present invention relates to prosthetic devices and more particularly to a conformable breast form containing a quantity of a liquid or a conformable gel.

15 The breast forms are especially designed for use as a breast form after a surgical operation. In such cases the figure of the person often presents an unpleasing appearance and the form is worn to maintain the normal figure or outline of the bust. In other instances, the forms are worn by women with small underdeveloped breasts in order to improve their figure.

20 25 It is important that the form be conformable to the shape of the breast or remainder of the breast of the wearer and of proper weight so that it may be worn for long periods of time without discomfort. Further, the form should be constructed that it constantly and automatically conforms to the remaining breast in shape and appearance, as that 30 that breast is affected by the position assumed by the wearer.

Heretofore, some forms have been made of wire reinforced padding, others have been made of flexible fabric stuffed with a filling such as hair, feathers or 40 cotton, still others have been molded of sponge rubber, in addition, air filled sacs and distendable sacs inflated with water have been used. These devices all have a relatively fixed shape, and a relatively constant volume, or are rather 45 inconformable and do not realistically reproduce the change in shape and the movement of a normal breast. Some of the prior devices have been generally

satisfactory for use when the wearer is in a standing position and not in motion. However, when the wearer assumes a sitting or prone position, or takes part in exercise, the movements of the prior art appliances are often unnatural and uncomfortable inasmuch as these appliances do not duplicate the changing shape of the remaining breast. The unnatural and uncomfortable position of the appliance is especially noticeable in women of middle age who make up the greater percentage of those with surgically removed breasts. The waist portion of an average person shortens about one to two inches when the person is seated. The apparent shortening is more pronounced in patients with faulty posture such as is frequently assumed post-operatively. The full slanting diaphragm and often large abdomen pushes the usual appliance higher when the person is seated. To counteract this movement, straps engaging with the corset or girdle are often used to pull the appliance downwardly. The strain set up by such straps not only causes discomfort at the shoulders but actually seriously interferes with the circulation of shoulder and arm and because of the recent operation often produces congestion. Moreover, in many cases, the prior appliances have been difficult or impossible to clean or renovate and when so cleaned often lose their original shape and present an unsightly appearance.

The present invention aims to overcome the foregoing difficulties and disadvantages by providing a form which is more natural in appearance and readily conforms to the shape of the natural bust regardless of the movements of the wearer, and that requires no special harness to wear.

Another object of the invention is to provide a form which is sanitary, and which may be washed easily and repeatedly without adversely affecting its wearability.

With these and other objects in view

the invention consists in a breast form comprising a conformable fluid retaining cell, a conformable, incompressible, in-expansible filler and a gas at approximately atmospheric pressure in said cell, the combined volumes of said filler and gas at least partially filling the total possible volume of the cell. The cell is adapted to be carried in the unmodified 10 cup of an ordinary brassiere, or in a brassiere cup provided with a retainer, or in the ordinary type of form-fitting bathing suit, so that in use, the cell is conformed to the shape and volume of the 15 available space between the brassiere, and the breast or the remainder of the breast, so as to produce the desired appearance. By reason of the fluid filling material, and the amount used, the cell is not distended or fixed in shape but automatically 20 assumes the shape and contour of the normal breast regardless of the position or movement of the wearer.

In one construction the fluid filling 25 material includes a foaming agent, so that under normal bodily movements, no appreciable sound caused by a movement of the contents may be detected.

In another construction of the form, it 30 is enclosed in an outer protecting envelope so as to prevent a sudden escape of the liquid in the event of a puncture or rupture of the retaining cell and the filling material includes an agent that coagulates upon evaporation, thus this cell 35 is substantially self-sealing.

In another construction of the invention, a cellular structure is provided within the retaining cell so as to impede the 40 movement of the liquid and thus to cause the form to more nearly simulate the normal movements of the natural breast.

In still another construction of the 45 invention the cell is partially filled with a conformable gel, and a gas at atmospheric pressure. This construction will not leak liquid if punctured, and in addition makes no audible sound when moved.

My breast form is advantageous in that 50 it readily conforms to the shape of the brassiere with which it is used or worn, regardless of its style, whether uplifted, pointed, rounded or pendulous, thus the wearer may use a brassiere of the same 55 style as worn before the breast removal and be assured that the outer clothing will fit without alterations. My breast forms mobility and softness to touch as well as its improved appearance are important 60 improvements over prior appliances. Further, the form has smooth and flowing characteristics and therefore readily conforms to the shape of the cavity left by the breast removal, and accordingly the 65 appliance may be worn soon after an

operation while tissues are still sensitive. Moreover, the breast form because of its smooth and flowing characteristics protects the sensitive area and prevents friction thereon due to the movement of the 70 arms or clothing. The form quickly assumes the body temperature and is more comfortable to the wearer as it radiates heat and feels cooler than many of the prior appliances. As its weight is 75 approximately that of the normal breast, no straps or other means are needed to hold it in position and its weight has a compensating effect in helping to overcome unequal shoulder carriage, which is 80 a frequent result of a major mastectomy.

The correct weight of the breast form reestablishes body balance. After a major mastectomy, a lack of such balance results in physical instability which often causes 85 mental instabilities and phobias in patients, such as fear of falling when descending stairs, and fear of walking on wet streets.

Other objects and advantages of the 90 invention will be apparent from the following description and from the accompanying drawings which show, by way of example, embodiments of the invention.

In the drawings:—

Fig. 1 is a perspective view of a breast 95 form worn with a brassiere and shown in position on a female figure, the conformable cell being positioned in a pocket in the brassiere and outlined in dotted lines.

Fig. 2 is a partial plan view of the cell.

Fig. 3 is a cross sectional view of the 100 cell and brassiere taken substantially along the line 3—3 of Fig. 1.

Fig. 4 is a view corresponding to Fig. 105 3 of a modified form of the cell showing a cellular structure within the cell formed of a plurality of small cells in liquid.

Fig. 5 is a view corresponding to Fig. 110 3 of a modified form of the cell showing a cellular structure within the cell formed of a plurality of pieces of a sponge-like material in liquid.

Fig. 6 is a view corresponding to Fig. 115 3 of a modified form of the cell showing a protective envelope enclosing the cell, the cell being filled with a preferred fluid.

Referring to the drawings, in Fig. 1 the fluid retaining cell 10, indicated in dotted lines, is located in the brassiere 120 cup 12 of brassiere 13 adapted to support and conform said cell, the assembly being worn on the female form as shown.

The brassiere 13 may be of any suitable form and is preferably of the same 125 type or shape as worn by the wearer before the mastectomy.

As shown in Fig. 3 the brassiere cup 12 is provided with a cell retainer 15 which may be a piece of soft textile material 130

sewn along the sides and bottom of the inside of the brassiere cup. A flap 16 is provided to cover the opening at the top of the brassiere cup.

5 As can best be understood by a comparison of Figs. 2 and 4, the cell 10 has a front wall 17 and a back wall 18, formed from a water impervious flexible sheet material, the peripheries of the walls 10 being joined together and sealed along the line 19. Alternately, the cell may be molded in one piece. The front wall 17 is convexo-concave in shape so as to more easily conform to the brassiere cup. The 15 rear wall 18 is generally flat though it may also be concavo-convex if worn as a breast form over underdeveloped breasts, or may be convexo-concave in the opposite direction if meant to fill a particularly large cavity resulting from a major operation.

In Fig. 2, end 20 of the cell, shown as broken away, may be extended or modified as necessary to fit along the auxiliary 25 side of the breast to fill a surgical cavity which may extend in that direction.

As shown in Fig. 2, an unsealed portion 21 of the cell 10 is provided as a means of placing the contents in the cell.

30 After this operation, this portion 21 is sealed.

As shown in Fig. 3 the cell 10 is at least partially filled with a comfortable filler 11, which may be a liquid or a conformable 35 gel, and gas 22 at atmospheric pressure.

Another embodiment of my invention is as shown in Fig. 4, in which the cell, constructed as above described, is at least 40 partially filled with a plurality of small cells 23 of preferably ellipsoidal shape. Each of the cells 23 is at least partially filled with conformable filler 11 which may be a liquid or conformable gel, and 45 a gas 22 at atmospheric pressure.

Surrounding the cells 23 is a filler 11, which is a liquid. The cell 10 is thus partially filled with the cells 23, and liquid filler 11 and gas 22 at atmospheric 50 pressure.

Another embodiment of my invention is as shown in Fig. 5, in which the cell constructed as above described, is partially filled with a plurality of bits of 55 flexible cellular material 24, such as cut rubber sponge, and a quantity of liquid filler 11 and gas 22 at atmospheric pressure.

Another embodiment of my invention 60 is as shown in Fig. 6. The fluid retaining cell 10 is enclosed in a flexible envelope 25, composed of a front wall 26, and a rear wall 27, made of a flexible fluid impervious material, the front and 65 rear walls being joined at their respective

peripheries and sealed along the line 28. Alternatively the envelope may be molded in one piece. The envelope 25 contains cell 10 plus a small quantity of gas 22 at atmospheric pressure. The envelope 25 70 may also contain a quantity of a highly water absorbent powder, such as Bentonite (not shown). Note that in Fig. 6, the liquid filler 11 and gas 22 contained in cell 10, is shown in a foaming condition 75 29. A conformable gel may also be used to fill cell 10.

It is of course apparent that the embodiment shown in Figs. 3, 4 and 5, may be combined with the outer envelope 80 shown in Fig. 6, and as described above.

The walls of the cells, both small and large, and the envelope described above, as in Fig. 6, are made of a flexible sheet material that is impervious to the passage 85 of water or air. My preferred material is a flexible sheet of the material sold under the Registered Trade Mark "Vinylite". The material is a highly plasticized copolymer of vinyl chloride and vinyl 90 acetate resin, and has the advantages of being cheaper and more flame resistant than rubber, is flexible at body temperature, and is resistant to the action of body perspiration. I have found that use of 95 "Vinylite" sheetstock twelve thousandths of an inch (0.012") thick results in a cell that is strong and durable, and commercially satisfactory.

The walls of the cell are joined together 100 by cementing, or if the material is "Vinylite", by sealing the edges together by the so-called "Electronic" sealing method which makes use of high frequency currents to accomplish the heat 105 sealing.

The contents of the cell are composed of gas at atmospheric pressure, and a filler which may be a liquid or a conformable 110 gel. Where, hereinafter in the claims or in the specification, the words "conformable filler" are used, it is intended to mean both a liquid and a conformable gel. These materials are incompressible, as distinguished from materials like sponge 115 rubber, and substantially inexpandable as distinguished from gases. My preferred liquid is water, to which I may add a foaming agent and a sealing agent. When less than all of a cell is filled with a 120 liquid, the liquid sloshes about and makes audible sounds when the cell is moved. Thus a foaming agent, which reduces these sounds to substantial inaudibility, overcomes the great disadvantages of a 125 flexible cell partially filled with a liquid. The advantages of incorporating a sealing agent, in case of a puncture or corrosion or rotting of the cell walls, is obvious. Other liquids which may be 130

used are; oils, emulsions of oil and water, soap mixtures, thickened oils, suspensions and emulsions in oil and water, silicon liquids such as Dow-Corning DC 5200 silicon fluid (a heat-stable, organo-silicon oxide polymer), and liquid latex.

I have found that the material known as "Vinylseal" adhesive W-125, which is a water-soluble plastic resin, containing 10 minimum solids of about 50% by weight, of which 1.5% by weight is monomeric vinyl acetate, and having a viscosity exceeding 3000 centipoises, a pH of 4.5 to 5.0 and a weight of 9.25 lbs. per 15 gallon at 60° F., and which is sold as an adhesive, also has the property of foaming when mixed with water and agitated. This mixture will also coagulate on evaporation, and when contained in the 20 cell, the cell being punctured, the mixture will function to seal the puncture. The self sealing effect is particularly good when the cell is in a second envelope (as shown in Fig. 6). When the double cell is punctured, very little liquid escapes completely, as most of it spreads in a thin film between the wall, and quickly forms a sealing clot.

Equal parts of the above water-soluble 30 resin and water, mixed together, produces a liquid having the desired viscosity and weight, it being important that the weight per unit volume of the cell, as worn (this volume generally being less than the unconfined volume of the cell) be approximately equal to the weight per unit volume of human tissue that is to be replaced, or duplicated. This mixture is maintained in a foamed condition by the 40 normal movements of the wearer of the form, and will seal satisfactorily. Variations of the above proportions of water and "Vinylseal" adhesive W-125, may be used depending on the viscosity, foaming 45 characteristics, and sealing qualities desired.

An amount of liquid or conformable gel 50 filler is used that will approximate the weight of tissue that has been removed. An amount of gas at atmospheric pressure, preferably air, is also allowed in the cell before sealing, this amount of air is necessary when using a liquid filler so that the liquid mixtures may foam and also to 55 produce a cell that can change in volume under pressure, and that will reproduce a volume under pressure corresponding to the volume of tissue lacking.

In order to achieve a comfortable, conformable cell, the possible total volume of the cell is generally not entirely utilized. This is simply accomplished by pressing a portion of the walls of the cell together after the conformable filler has been put 65 in the cell, and during the final sealing

step. The amount of fluid filler should not fill the available space, some space being left for air. The cell is sealed with the entrapped liquid or conformable gel and air generally filling only a portion of 70 the total possible volume of the cell.

As an example, in my manufacture of cells for certain prosthetic uses, not requiring special individual fitting, I have found that it is necessary to provide a complete range of sizes for both left and right breasts. Of course, each size breast is different in weight and shape from the others. The cells all have flat back walls, the wall material being conformable 80 enough to fill in around uneven scar tissue formations over the chest, and at the axillary region.

However, I have found that in manufacturing all these ready-made forms that the proportions of gas and conformable filler are about the same. I generally fill each cell 60% full (of its possible total volume) with conformable filler, and leave approximately 10% to 15% of the 90 cell volume as "dead space". The remainder of the possible volume of the cell is filled with air at about atmospheric pressure. In my manufacture of cells for cosmetic purpose, the cells are 95 different in shape and weight than the aforementioned cells. The proportions and amounts of the filler, gas and "dead space" employed in the cell depend on the volume and shape of the breast tissue 100 to be replaced.

As shown in my examples in Figs. 3 and 6, a conformable gel may be used to partially fill the cell 11. The conformable gel is used as above described for the use 105 of liquid. A suitable conformable gel material is the product known as "bouncing putty", a linear polymer resulting from a hydrolysis of dimethyl dichlorosilane, grade 9991-1 manufactured by the General Electric Company. Said "bouncing putty" may be modified with oil, grease, or substances containing CH<sub>3</sub> groups to increase the rate of flow. A single cell structure, partially 115 filled with this material, is quiet in use and will not leak. Another suitable gel is a starch and water paste, mixed with a suitable preservative.

As shown in my example in Fig. 4, the 120 small cells 23 may be partially filled with conformable gel in place of liquid, while the cell 11 is partially filled with liquid.

By reason of the plurality of cells shown in Fig. 4, or the cellular material 125 shown in Fig. 5, contained in the retaining cell, a somewhat more gradual change in the shape of the retaining cell occurs as the wearer assumes different positions. These cells thus very closely 130

approximate the shape changes of the normal breast.

Having now particularly described and ascertained the nature of my said invention and in what manner the same is to be performed, I declare that what I claim is:—

1. A breast form comprising a conformable fluid retaining cell, a conformable, 10 incompressible, inexpandable filler and a gas at approximately atmospheric pressure in said cell, the combined volumes of said filler and gas at least partially filling the total possible volume of the cell.
2. A breast form comprising a liquid impervious cell of flexible material, a conformable liquid filler and a gas at approximately atmospheric pressure within said cell, said filler being substantially noiseless when agitated by normal body motion, the said filler occupying a major portion of the volume of said cell and the combined volume of said filler and gas being less than the total possible volume 25 of said cell.
3. A breast form according to Claim 1 or 2, in which the volume of said filler is approximately 60% of the total possible volume of said cell and the volume of said 30 gas is approximately 30% of said total possible volume.
4. A breast form according to Claims 1, 2 or 3, in which the conformable filler is a foaming liquid.
5. A breast form according to Claim 1, 35 2 or 3, in which said filler comprises a liquid.
6. A breast form according to Claim 1, 2 or 3, in which said filler comprises a 40 conformable gel.
7. A breast form according to Claim 5, in which the liquid is adapted to coagulate upon evaporation.
8. A breast form according to any of 45 the preceding claims, comprising a flexible outer envelope impervious to fluids enclosing said cell, whereby said form will seal itself when punctured.
9. A breast form according to any of 50 the preceding claims comprising a plurality of smaller cells within said fluid retaining cell, said fluid at least partially

filling said smaller cells and the remaining space between said smaller cells and said retaining cell. 55

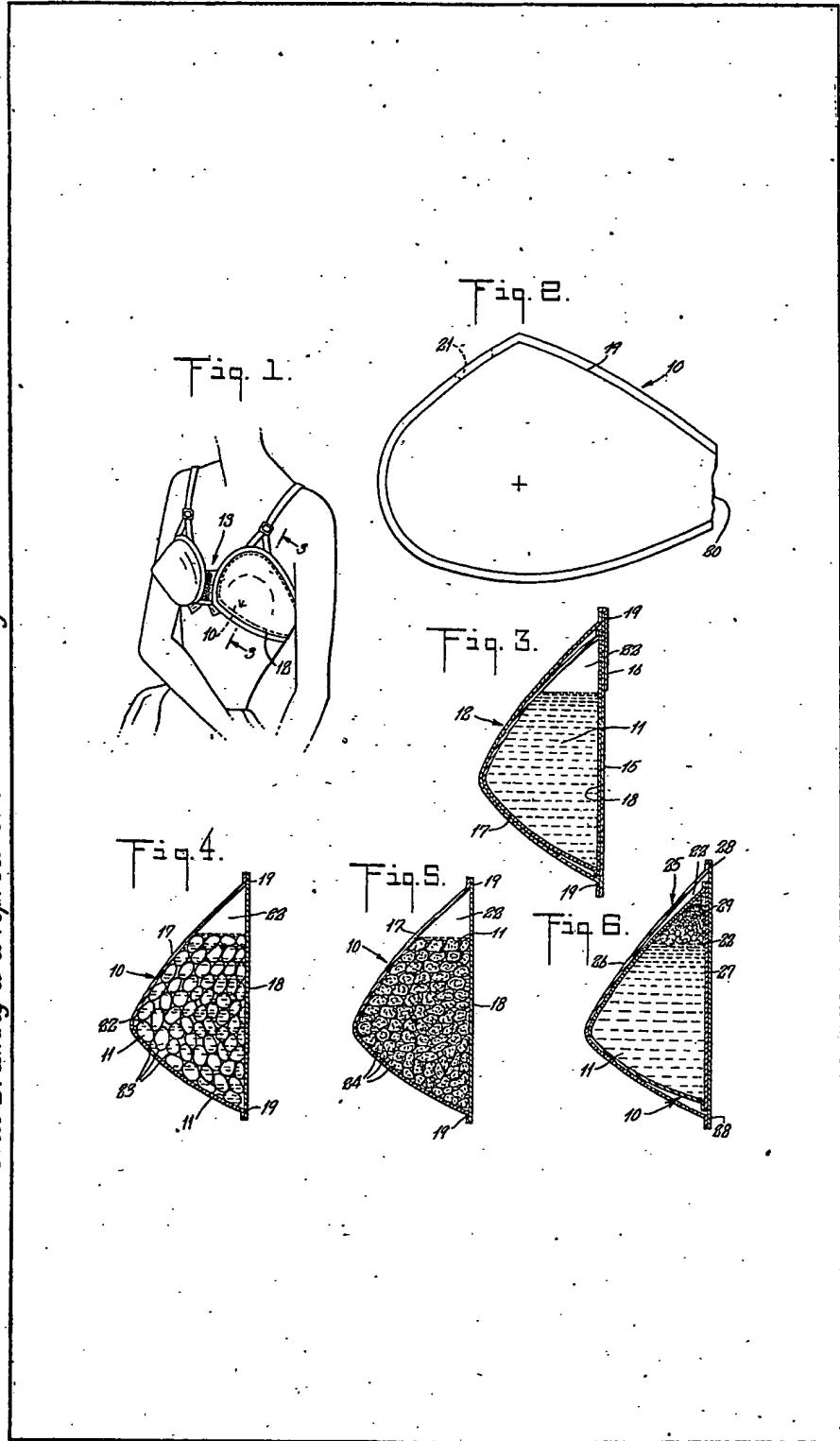
10. A breast form according to any of the preceding claims, comprising a plurality of pieces of sponge-like material within said retaining cell in addition to said fluid. 60
11. A breast form according to any of the preceding claims, in which the front and rear walls of said retaining cell are formed of flexible plastic resin.
12. A breast form according to Claim 65 11, in which the resin comprises the plasticized copolymers of vinyl chloride and vinyl acetate. 70
13. A breast form according to any of Claims 8—12, in which the front and rear walls of said envelope are formed of a flexible resin comprising the plasticized copolymers of vinyl chloride and vinyl acetate.
14. A breast form according to any of 75 Claims 1—5 or 7—13, in which the filler comprises a mixture of water and a water solvent resin adapted to foam upon agitation and to coagulate upon evaporation.
15. A breast form according to Claim 80 14, in which the water solvent resin is "Vinylseal" adhesive W—125.
16. A breast form according to Claim 15, in which the proportion of water and "Vinylseal" adhesive W—125 are 85 approximately equal to each other.
17. A breast form according to any of the preceding claims, in which the weight per volume of said filler and gas is approximately equal to the weight per 90 unit volume of human tissue.
18. A breast form constructed and arranged substantially as hereinbefore described with reference to and/or illustrated in any of the figures of the accompanying drawings. 95

Dated this 20th day of May, 1949.

HASLTINE, LAKE & CO.,  
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London, W.C.2, and  
19—25, West 44th Street, New York,  
U.S.A.,  
Agents for the Applicant.

POOR  
QUALITY

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